

REMARKS

Claims 14, 17, 19, 20 and 32-42 are pending in the application with entry of this Amendment. Claims 32-34 and 42 are currently amended. The amendments do not present new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicants acknowledge that the following prior rejections have been withdrawn:

- A. Rejection of claims under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,309,909 to Gadsby (“Gadsby”).
- B. Rejection of claims under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff.
- C. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Tetzlaff in view of U.S. Patent No. 6,162,220 to Nezhat.

II. Withdrawn Indication of Allowed Claims

Applicants note that claims 32-37, 40 and 41 were indicated to be allowed in the Office Actions dated May 21, 2007 and March 24, 2008. Now these claims stand rejected. Applicants kindly note that “Whenever on examination, any claim of a patent is rejected, . . . the Director shall notify the application thereof, stating the reasons for such rejection, . . . together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application . . .” and “In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command...”). 35 U.S.C. §132; 37 C.F.R. § 1.194(c)(2).

III. Claims 14, 17, 19, 20, 32 and 33 are Patentable Over Gadsby and Rau

Independent claims 32 and 33 and respective dependent claims 14, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,309,909 to Gadsby (“Gadsby”) in view of U.S. Patent No. 4,685,466 to Rau (“Rau”). Applicant respectfully traverses the rejection and respectfully submits that rejection is moot in view of the

deficiencies of the cited references, individually and in combination, and the manner in which the Office Action misconstrues what is actually disclosed in certain references.

With regard to independent claims 32 and 33 and respective dependent claims 17 and 18, it is alleged that penetration tines 18 described by Gadsby are, or form, “tissue stimulation electrodes(s).” Office Action (p. 3, lines 2-3). However, this is not what Gadsby actually discloses. It is clear from Gadsby that the penetration tines 18 are not and do not form a tissue stimulation element.

First, the tines 18 described by Gadsby are used to penetrate the skin to adjust the skin’s impedance (Gadsby, col. 2, line 50). They are not involved in tissue stimulation. To support the rejection, the Office Action has merely referred to these tines 18 and generally alleges, without more, that such tines are or somehow form a “stimulation element” as recited in claims 32 and 33. For example, the Office Action is understandably silent as to how such tines 18 are or form a “stimulation” element when the tines 18 configured as described by Gadsby are not even connected to a source of stimulation energy and do not emit stimulation energy. No such description is provided within the cited reference. Instead, the tine structures 18 are used to penetrate skin to alter the skin’s surface and resistance thereof. More particularly, as described by Gadsby, the purpose of the tines 18 is to reduce the effects of motion artifacts, *i.e.*, variations in skin resistance that occur through compression or extension of the layers of the skin surrounding the electrode. Gadsby (col. 3, lines 5-9; col. 4, lines 43-46, 60-64). Thus, the impedance adjustment is the result of tines 18 penetrating the skin, not application of stimulation energy and not serving as stimulation elements. Therefore, the tines 18 are not and do not form a “stimulation element” and are not related to such a configuration, and the tine structures 18 described by Gadsby are not related to the claims of the subject application. Applicant also notes that it is improper to ignore elements of a claim, *i.e.*, the term “stimulation” of “stimulation elements” cannot be ignored.

Further, the Office Action has not identified any source of stimulation energy that is connected to the tines 18. This is consistent with the fact that no such configuration is described by the cited reference.

Moreover, the Office Action has not addressed the fact that the tines 18 are not part of the conductive path as described by Gadsby. For example, Gadsby describes tines 18 that extend from an inner surface of a dome 16, and an eyelet 34 and stud 36 combination that is coupled to

the conductive pad 22. A snap connector 38 releasably connects the eyelet/stud combination to a conductor 40, which in turn is coupled to medical and diagnostic equipment (not shown). Gadsby (col. 3, line 67 – col. 4, line 3). “Thus, a conductive path is formed between the electrolytic gel in the conductive pad 22 and the medical and diagnostic equipment. Gadsby (col. 4, lines 4-6). See also, Gadsby (col. 5, lines 29-49). As would be expected with the particular configuration described, the sections of Gadsby that describe a conductive path do not even refer conduction through the tines 18 extending from the dome 16 since the tines 18 are not part of the conductive path. The Office Action has also failed to address these facts.

Consistent with these conclusions based on what is actually disclosed by the cited reference is the fact that the cited sections of Gadsby explain that the penetration tines 18 are “preferably formed of rigid plastic.” Gadsby (col. 4, line 65). The Office Action has not established how such tines 18 are or form a “stimulation element.”

Also consistent with these conclusions, and based on what is actually disclosed by the cited reference, is the fact that the Gadsby explains that tines 18 are pushed into and withdrawn from the patient’s skin “**prior** to acquiring biopotentials” *i.e.*, the tines 18 are not even used to acquire or transmit biopotential energy or signals. Gadsby (Abstract; col. 3, lines 7-10) (emphasis added). In other words, the tines are withdrawn before the medical and diagnostic equipment (which is not even connected to the tines 18) is utilized and, therefore, the tines 18 are not related to use of stimulation energy, are not within the conductive path described by Gadsby, and are not used during acquisition of biopotentials. Again, the Office Action has failed to address all of these determinative facts.

If the rejection stands, Applicant requests the Examiner to explain how a penetration tine(s) 18, which are used before medical and diagnostic equipment is utilized is a “stimulation” element and emits “stimulation energy” and to further explain how the cited plastic tines 18 are coupled to a source of stimulation energy such that the penetration tines can actually function as stimulation elements.

Second, it is alleged that such penetration tines 18 have a diameter of about 0.5 to 1.0mm. Office Action (p. 3, line 3). The Office Action, however, has not cited any section of Gadsby that actually describes this structural feature. Otherwise, Gadsby explains that the tines 18 preferably have a length of 4mm. Gadsby (col. 4, lines 34-35, 64-66).

Third, it is alleged that the size of the tines 18 (alleged stimulation element) is too small to form a transmural myocardial lesion, but as described above. However, as explained in detail above, the tines 18 are not stimulation elements, are not even coupled to a source of stimulation energy, do not emit stimulation energy, are not part of the conductive path described by Gadsby, and naturally, are not related to formation of myocardial lesions. Rather, the device described by Gadsby is configured for attachment to the skin, not the heart, and as explained above, are used “**prior** to acquiring biopotentials” *i.e.*, the tines 18 are not even used to acquire or transmit biopotential energy or signals since they are withdrawn before the medical and diagnostic equipment (which is not even coupled to the tines 18) is utilized.

Given the deficiencies of Gadsby discussed above, if it is alleged that it is inherent that the tines 18 are structured and function as recited in claims 32 and 33, Applicant notes again that the Office Action has not set forth why it is inherent that the tines 18 are necessarily structured and function as recited in Applicant’s claims particularly considering that Gadsby is silent as to what is alleged in the office Action, Gadsby does not describe the tines 18 as being connected to a source of stimulation energy, and further explains that the tines 18 are pushed into and withdrawn from the patient’s skin for a purpose other than acquiring biopotentials and **prior** to acquiring biopotentials, *i.e.*, they are not used for acquiring biopotential energy or signals.

For the Examiner’s reference, Applicants again note MPEP §2112 (to establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.) To establish inherency, extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art; a claim limitation is inherent in the prior art if it is necessarily present in the prior art, not merely probably or possible present) (emphasis added).

Fourth, it is conceded that Gadsby fails to disclose “means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure” as recited in claim 32 and “an anchor, associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue” as recited in claim 33. Office Action (p. 3, lines 5-9; p. 4, lines 5-8). Rau is relied upon for this limited purpose. Rau, however, does not cure the deficiencies of Gadsby and has its own deficiencies. Thus, the cited references, individually and even if somehow properly combined, cannot support the rejection.

With regard to Rau and claim 32, it is apparently alleged a leading-in tube 4 that is used to connect a mount 2 in the form of a suction cup to a vacuum line is the “means” recited in claim 32. However, with regard to the “means” recited in claim 32, the subject application does not even refer to a vacuum component. Thus, the basis of the rejection is not clear. If the rejection stands, Applicant requests the Examiner to identify a vacuum in the context of the “means” and how the cited references apply to claim 32.

With regard to Rau and claim 33, it is apparently alleged that the same mount 2 in the form of a suction cup and leading-in tube 4 is “an anchor, associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue” as recited in claim 33. Specifically, it is alleged that the “suction cup (2 and vacuum line 4) is an “anchor” as recited in claim 33. As recited in claim 33: 1. the anchor is associated with the tissue stimulation element, 2. the anchor is configured to secure the surgical apparatus to tissue, and 3. this is done by the anchor piercing tissue and pressing the stimulation element against the tissue.

However, as conceded in page 4 of the Office Action, Rau describes a suction cup 2 and use of a vacuum and a leading-in tube 4. As is well understood, neither the suction cup 2 nor the leading-in tube 4 is configured to pierce tissue, and the Office Action has not explained how a suction cup 2 described by Rau would be utilized in this regard. Rather, as described by Rau, and consistent with the understanding of a person of ordinary skill in the art, suction is used to attach the device “on the skin surface” Rau (col. 5, line 10). This does not involve piercing tissue. Thus, tissue is not pierced by the suction cup 2, the cited suction cup 2 and leading-in tube 4 components are not relevant to the “anchor” as recited in claim 33, and the Office Action

allegations are misplaced by relying on an interpretation of the cited references that goes beyond what is actually described by the cited references

Further, Applicants note that with regard to Gadsby and Rau, Gadsby relates to a device having tines 18 that are not coupled to a source of energy and are not within a conductive path. With this particular configuration, before biopotentials are acquired, the tines 18 penetrate the skin, and are then fully withdrawn from the skin and returned to a first position. After the tines 18 are removed, biopotentials are acquired. Gadsby (col. 2, lines 59-66; col. 3, lines 6-10; col. 4, lines 12-14, 30-31; col. 5, lines 67-68). In contrast, Rau describes a device that includes needle points 1 that are connected electrically to a conductor 3 or retained within a conductive mounting 2a. Thus, the tines 18 (Gadsby) and points 1 (Rau) are configured and utilized in opposite manners, and it is not necessary to combine the references as alleged. Rau also explains that “There is no need to use electrode paste or electrode jelly which are usually required on conventional surface electrodes.” Rau (col. 3, lines 1-3). In contrast, Gadsby is specifically directed to a configuration in which a conductive pad 22 is “saturated with electrolyte gel.” Gadsby (col. 3, lines 58-59). The device described by Rau is operable as a result of a conductive path that is formed between the electrolyte gel in the conductive pad 22 and the medical and diagnostic equipment. Thus, Gadsby and Rau describe devices that are configured and operate in opposite manners.

Further, given the manner in which the device described by Gadsby is structured, it would not be obvious, and it is not necessary, to apply vacuum to the device described by Gadsby since Gadsby explains that the device is attached to the skin by removing a release liner 24 and applying the device to the skin using an adhesive support structure 20. Gadsby (col. 3, lines 1, 53-67). A vacuum would unnecessarily complicate the structure of the device described by Gadsby, and the Office Action has not explained how or why this would be done.

Accordingly, Applicant respectfully submits that independent claims 32 and 33 are patentable over Gadsby and Rau, individually and even if somehow properly combined. Dependent claims 14, 17, 19 and 20 depend from and incorporate the elements of independent claims 32 and 33 and, therefore, are also believed patentable over the cited references.

Further, Gadsby fails to disclose, teach or suggest and is not related to “wherein the tissue stimulation element comprises a stimulation electrode” as recited in claims 14 and 17 since, as explained in detail above, the tines 18 are not electrodes, and are not stimulation

electrodes, are not connected to a source of stimulation energy, are not within the conductive path as described by Gadsby, and are removed before any biopotentials are measured.

Additionally, with regard to claims 19 and 20, independent claim 33 recites that the anchor is configured to secure the surgical apparatus to tissue by piercing tissue and pressing the stimulation element against the tissue, but the cited suction element described by Rau clearly is not configured in this manner.

Accordingly, Applicant respectfully request that the rejection of claims 14, 17, 19, 20, 32 and 33 under 35 U.S.C. §103(a) be withdrawn.

IV. Claims 34-37 and 40-42 are Patentable Over Gadsby and Daddona

Independent claim 34 and dependent claims 35-37 and 40-42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gadsby in view of U.S. Patent No. 6,091,975 to Daddona *et al.* (hereafter “Daddona”). Applicant respectfully traverses the rejection and respectfully submits that rejection is moot in view of the deficiencies of the cited references, individually and in combination, and the manner in which the Office Action misconstrues what is actually disclosed in certain references.

Initially, Gadsby fails to disclose, teach or suggest “first and second tissue stimulation elements” as recited in claim 34. It is alleged that portions of the tines 18 are “tissue stimulation electrodes” but as explained in detail above in Section III, this is not what is described by Gadsby. Contrary to the Office Action allegations, the tines 18 or portions thereof are not and do not form a tissue stimulation element, are not even connected to a source of stimulation energy (which the Office Action has failed to identify), do not emit stimulation energy, are not part of the conductive path as described by Gadsby, and are pushed into and withdrawn from the patient’s skin **prior** to acquiring biopotentials. Thus, the tines 18 are not even related to stimulation elements, and the Office Action has failed to address all of these determinative facts. Applicant also notes that it is improper to ignore elements of a claim, i.e., the term “stimulation” of “stimulation elements” cannot be ignored.

Further, Gadsby fails to disclose, teach or suggest a flexible carrier that is movable between an unstressed state and a deflected and stressed state and that also carries stimulation electrodes as recited in claim 34 since, as explained above, the cited tines 18 cannot support the rejection.

It is also conceded that Gadsby also fails to disclose, teach or suggest “a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state” as recited in claim 34. Office Action (p. 5). Daddona is apparently cited in this regard, and page 5 of the Office Action cites microprotrusions 4 described by Daddona. Daddona, however, cannot support the rejection and does not cure the deficiencies of Gadsby. Thus, the cited references, individually and even if somehow properly combined, cannot support the rejection.

Certain microprotrusions 4 described by Daddona include electrodes 14, 16 and 18 that are in electrical communication with a control unit 10 through traces 20. Daddona (col. 3, line 67 – col. 4, line 2). The electrodes 14, 16, 18 are part of an electrochemical sensor 22 configured for detection of agents such as body electrolytes. Daddona (col. 1, lines 5-9). For this purpose, the electrode 14 includes glucose oxidase to define a sample electrode, the electrode 16 is a counter electrode, and the electrode 18 is a reference electrode. The resulting readings acquired by the electrodes 14, 16, 18 are provided to the control unit 10. Thus, such electrodes 14, 16, 18 of the electrochemical sensor 22 are not stimulation elements as recited in claim 34. Further, Daddona and the Office Action are understandably silent as to microprotrusions 4 being stimulation elements and being configured to emit stimulation energy. Further, the microprotrusions 4 are not carried by a curved inner portion of a carrier. Rather, as shown in Fig. 3, for example, the microprotrusions 4 extend from a surface of a plate 6 that is flat.

Additionally, with regard to Gadsby and Daddona, Gadsby is related to a device that uses tines 18 to reduce motion artifacts when recording biopotentials. Gadsby (Abstract). On the other hand, Daddona is related to a very different device used for a very different purpose, i.e., an electrochemical sensor configured for detection of agents such as body electrolytes. Further, as explained above in Section III, Gadsby relates to a device having tines 18 that are not coupled to a source of energy and are not within a conductive path. With this particular configuration, before biopotentials are acquired, the tines 18 penetrate the skin, and are then fully withdrawn from the skin and returned to a first position. After the tines 18 are removed, biopotentials are acquired. Gadsby (col. 2, lines 59-66; col. 3, lines 6-10; col. 4, lines 12-14, 30-31; col. 5, lines 67-68). In contrast, Daddona describes a device that includes electrodes 14, 16, 18 on microprotrusions 4 and that are in electrical communication with a control unit 10 through traces

20. Daddona (col. 4, lines 1-2). Thus, the tines 18 (Gadsby) and microprotrusions 4 (Daddona) are configured and utilized in opposite manners, and it is not necessary to have microprotrusions 4 to provide a conductive path which, as explained by Gadsby, is already formed between the electrolytic gel in the conductive pad 22 and the medical and diagnostic equipment, *i.e.*, from the medical equipment, through the eyelet 34, conductive pad 22 and to the patient's skin 30. Gadsby (col. 4, lines 4-6; col. 5, lines 29-49).

Further, given the manner in which the device described by Gadsby is structured, it would not be obvious, and it is not necessary, to utilize the microprotrusions 4 to secure the device described by Gadsby to the skin since this is already done using an adhesive 20 and release liner 24. Gadsby (Fig. 2).

Additionally, it is apparently alleged that it would be obvious to replace the tines 18 with microprotrusions 4, but the Office Action has not addressed how, or why, this would be done given the fact that the tines 18 project from a dome 16, which forms part of an enclosure 44. Gadsby (col. 5, lines 10-11). Relatedly, the Office Action has failed to explain how the microprotrusions 4 (which are made using a photolithography and chemical etching process), would be fabricated upon the curved, resilient dome 16, and how such microprotrusions 4 would be electrically connected, particularly considering that Gadsby explains that during use, a user (42) pushes upon the outer surface of the dome 16. Gadsby (Fig. 4).

Applicant respectfully submits that independent claim 34 is patentable over Gadsby and Daddona, individually and even if somehow properly combined despite the devices described by these two references being very different structurally and functionally. Dependent claims 35-37 and 40-42 depend from and incorporate the elements of independent claim 34 and, therefore, are also believed patentable over the cited references, and remarks regarding the deficiencies of the cited references and the Office Action allegations with respect to certain dependent claims are discussed above in Section III.

Accordingly, Applicant respectfully request that the rejection of claims 34-37 and 40-42 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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